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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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05/405,400

05/23/99

O'REILLY

M

05213-0640

HM12/1219

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EXAMINER

HUFF, S

ART UNIT

PAPER NUMBER

1642

5

DATE MAILED:

12/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/405,499

Applicant(s)  
O'Reilly et al

Examiner  
Sheela J. Huff

Group Art Unit  
1642



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 52-73 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 52-73 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

### DETAILED ACTION

1. Claims 52-73 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. Claims 52-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses the isolation of endostatin protein characterized by its molecular weight, N-terminal sequence and ability to inhibit endothelial cell proliferation in vitro. The endostatin protein is disclosed to be identical to a specific fragment from collagen XVIII, which sequence is also present in collagen XV or BOVMPE1 and may be present in other collagen proteins. This fragment is characterized by its size, its heparin binding ability, its sequence, and location within collagen XVIII, and its ability to inhibit endothelial cell proliferation. Thus, endostatin (as defined by the specific fragment from collagen XVIII and/or the N-terminal 20 amino acid sequence of SEQ ID No. 1) may be isolated from other sources. However, the claims are limited to endostatin as defined in the specification with regard to its origin, characteristics and activity. The number of fragments and proteins encompassed by the language "protein is an amino acid sequence of a C-terminal region fragment of a

Art Unit: 1642

collagen protein" are virtually limitless. The claims refers to endostatin as defined as a protein comprising any sequence from a C-terminal fragment from any collagen protein, so long as the fragment inhibits endothelial cell proliferation. There is no guidance regarding what sequence of amino acids found within even a defined fragment would be predicted to inhibit endothelial cell proliferation. There is no guidance regarding which fragments, of what size, from what region, within the C-terminus would be predicted to inhibit endothelial cell proliferation. There is no guidance regarding which collagens are predicted to possess such sequence. Further, there is no guidance regarding the content of the rest of the protein, in addition to the amino acid fragment. The specification specifically discloses that not only is the sequence of the fragment vital to endostatin activity, but also that additional sequence added to the definitive fragment is vital. Page 44 discloses that longer fragments of the specific region are not active. While, recombinant techniques are available, it is not routine in the art to screen large numbers of substituted proteins where the expectation of obtaining similar activity is unpredictable based in the instant disclosure. In the case, the number of proteins encompassed is virtually limitless and it would require undue experimentation to screen each and every one of limitless numbers of proteins encompassed to determine if they perhaps inhibit endothelial cell proliferation.

Art Unit: 1642

3. Claims 53 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of these claims, the terminology "non fibrillar collagen protein" renders the claim vague and indefinite. What regions are encompassed by this terminology?

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 52-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 17-23 of U.S. Patent No. 5854205. Although the conflicting claims are not identical, they are not patentably

Art Unit: 1642

distinct from each other because the only difference between the two inventions is the scope of the claimed endostatin.

6. Claims 52-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 15-17 and 19-20 of copending Application No. 09/315689. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two inventions is the scope of the claimed endostatin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday and Thursday from 5:30am to 2:00pm.

Art Unit: 1642

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Tony Caputa, can be reached on (703)308-3995.

The FAX phone number for the group is (703)308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[anthony.caputa@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff

December 15, 2000

Application/Control Number: 09/405499

Page 7

Art Unit: 1642

A handwritten signature in black ink, reading "Sheela J. Huff". The signature is written in a cursive style with a large, stylized "S" and "H".

Sheela J. Huff

Primary Examiner